In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1303V

(to be published)

TARA DENNINGTON,	*	
	*	Chief Special Master Corcoran
Petitioner,	*	Filed: March 23, 2023
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for Petitioner.

Tyler King, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On August 28, 2018, Tara Dennington filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioner alleges that a tetanus, diphtheria, and acellular pertussis ("Tdap") vaccine she received on August 30, 2015, caused her to incur Guillain-Barré syndrome ("GBS"). *Id.*

The parties have agreed that the matter could reasonably be resolved via ruling on the record, and filed briefs in support of their respective positions. *See* Petitioner's Motion, dated April

[1] This Decision will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the Decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

22, 2022 (ECF No. 46) ("Mot."); Respondent's Opposition, dated July 7, 2022 (ECF No. 53) ("Opp."); Petitioner's Reply, dated August 1, 2022 (ECF No. 55) ("Reply"). Having reviewed the above plus the filed medical records, expert reports, and associated literature, I hereby deny an entitlement award. As discussed in greater detail below, Petitioner has not preponderantly established that the Tdap vaccine he received could cause GBS, or that it did so to her in a medically-acceptable timeframe.

I. Fact History

Pre-Vaccination History and Previous GBS Diagnosis

Petitioner had a prior medical history of abdominal pain, allergic rhinitis, gastroesophageal reflux disease, asthma, obsessive-compulsive disorder, anxiety, and irritable bowel syndrome. Ex. 12 at 7; Ex. 14 at 5–7. Significantly, she had previously suffered from GBS (Miller-Fisher variant) in 2005, which left her with bilateral hearing loss, weakness and fatigue. Ex. 9 at 42.

Ms. Dennington's earlier bout of GBS began approximately ten years earlier, in 2005, when she was 15 years old. Records submitted from this period do not report *any* vaccine (let alone a Tdap vaccination) being administered close-in-time to the illness,[3] and also indicate that a week prior to visiting the emergency room, she had "developed a fever with a mild headache and neck pain." Ex. 16 at 20, 24–25; Ex. 22.

Petitioner eventually visited South Hermann emergency room and Texas Children's Hospital ("TCH") in Houston, Texas, on August 21, 2005, for complaints of bilateral facial paralysis, weakness, and ataxia, and was thereafter hospitalized until the end of that month. Ex. 16 at 20, 24–25. While hospitalized, a head CT scan and lumbar puncture were performed. *Id*. The CT scan was reportedly normal and the lumbar puncture reportedly showed no white blood cells, a protein level of 123, and normal glucose. *Id*. She complained of unsteadiness/dizziness with lightheadedness that was worse when she sat or stood up. *Id*. A pediatric neurologist performed a consultation the following day and expressed the suspicion that Petitioner was suffering from GBS or possible spinal cord demyelination. *Id*. An MRI of the spine was normal, however, with no evidence of demyelination. Ex. 16 at 23.

According to a progress note written on August 24, 2005, Petitioner was diagnosed with GBS with bulbar involvement and transferred out of the pediatric intensive care unit to the

[3] Petitioner filed a record titled "complete Vaccination Records," but this record does not identify the source of its information, the entity responsible for creating this record, or the basis for the information included in the chart. Ex. 22. This document indicates that Petitioner received Tdap vaccine doses several times in the several times in the *years* before this illness. *Id*. But the dose administered closest in time to her first GBS diagnosis (in August 2005) occurred 15 months before, in 2004. Petitioner otherwise acknowledges that the record does not establish she received any Tdap vaccine dose right before onset of her GBS symptoms at this prior time. Mot. at 28.

progressive care unit.[4] Ex. 16 at 25. After treatment with IVIG[5] she was to be transferred again for continued rehabilitation. *Id*. at 25, 27. Petitioner underwent a rehabilitation evaluation at TCH on August 26, 2005, and the record from it noted no cognitive impairment but difficulty with some activities of daily living ("ADLs") due to ataxia. *Id*. at 27. She also had impaired oral motor function due to facial weakness but no gagging with oral intake. *Id.* She was scheduled for physical, occupational, and speech therapy.[6] *Id*. at 28.

Petitioner saw neurologist Aloysia Schwabe, M.D., of Physical Medicine and Rehabilitation Services at TCH, for follow-up on October 31, 2005. Ex. 16 at 37. Petitioner reported persistent fatigue that affected her ability to participate in physical and occupational therapy. *Id*. She continued occupational, physical, and speech therapy three times per week. *Id*. She demonstrated improved strength and balance and was walking independently. *Id*. Petitioner saw Dr. Schwabe again on January 9, 2006, complaining of persistent fatigue since October 2005. Ex. 16 at 40–41. Her facial weakness persisted into the summer, although her overall motor function had somewhat improved. Ex. 16 at 44–45. Otherwise, she received physical, occupational, and speech therapy until she was discharged in April of 2006.

On November 16, 2006, Petitioner returned to TCH for a neurologic follow-up. Ex. 16 at 47. It was noted that she still suffered from a lack of energy and was fatigued easily, with some lingering facial symptoms despite improvement. *Id.* Almost three years later,[7] on September 11, 2009, Petitioner had another neurology consultation at the Houston Neurological Institute, where she was seen by neurologist Kathleen Eberle, M.D. Ex. 10 at 1. Dr. Eberle agreed that Petitioner's presentation was suggestive of the "Miller Fisher variant of [GBS] and/or Bickerstaff's brainstem encephalitis." *Id.* An electromyogram ("EMG")[8] performed on January 7, 2010, showed evidence

[4] It was reported that prior to her presentation at TCH, Petitioner had a seven-day history of nasal congestion and headache, and had been diagnosed by her primary care physician as sinusitis and sent home on antibiotic therapy. Ex. 16 at 25. When she developed facial drooping, Petitioner returned to the emergency room and was subsequently transferred to TCH. *Id*.

[5] Intravenous immunoglobulin ("IVIG") is a blood product used to treat patients with antibody deficiencies, including neurological disorders. Clinical Uses of Intravenous Immunoglobulin, NCBI (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1809480/ (last visited on Mar. 23, 2023).

[6] Petitioner provided a letter from Neurodevelopmental Therapy Services ("NTS") dated September 15, 2005, indicating that Petitioner was admitted to their clinic on September 6, 2005 for occupational, physical, and speech therapy. Ex. 21 at 1. NTS indicated that they no longer had records of the services provided as they had been destroyed in accordance with the state of Texas rules for retention of such records. *Id*. at 2.

[7] There are no records of care filed in this case for the timeframe between November 2006 and September 2009.

[8] Electromyography is the process by which "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface electrodes, needle electrodes, and devices for amplifying, transmitting, and recording the signals." *Electromyography,* Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited Mar. 23, 2023).

of a "chronic sensorimotor neuropathy, predominantly demyelinating." *Id*. at 5. That same month, Dr. Eberle wrote a letter addressed "to whom it may concern" stating that Petitioner had been diagnosed with a variant of GBS in 2005, and that she had "never achieved full recovery." Ex. 19 at 1.

2015 Vaccination and GBS Treatment

On August 30, 2015, Petitioner (now 25 years old) was seen at the Kingwood Medical Center emergency room ("Kingwood") in Kingwood, Texas for a rash and abscess. Ex. 6 at 29. Petitioner reported that she had scraped her foot on an old rusty pole and had mild pain, but no fever, chills, or drainage from her wound. *Id*. She received the Tdap vaccine and was advised to keep the wound clean and dry. *Id*. at 31; Ex. 1 at 1.

Two days later, on September 1, 2015, Petitioner returned to Kingwood with complaints of numbness and tingling that was worse in her lower extremities. Ex. 6 at 11 (reporting that her "foot just kinda feels asleep"). She denied chest pain and shortness of breath. *Id.* She also reported receiving a tetanus vaccination two days earlier, and that she had a medical history of GBS. *Id.* Physical examination did not document any abnormalities. *Id.* at 12–14. Approximately two hours after arriving at Kingwood, Petitioner's mother stated that Petitioner needed to see a neurologist, and Petitioner and her mother left Kingwood "against medical advice." *Id*. at 11–15.

Petitioner presented to TCH that same day. Ex. 8 at 3. She provided a history of numbness of the left side of the face, leg, and toes. *Id*. Petitioner's mother reported that Petitioner had been seen at TCH in 2005 "with [the] same complaints after [she] received a [t]dap vaccination," and was then diagnosed with GBS (although the record as discussed does not indicate she received the Tdap vaccine in 2005). *Id*. Petitioner also, however, reported a two-day history of a subjective fever and nausea earlier in the day. *Id*. The attending resident noted that it was an "[i]nteresting presentation of parasthesia and numbness which the patient states was very similar to onset of her previous episode of [GBS]." *Id.* Upon examination, she had a normal respiratory exam and no headaches or neck rigidity. *Id*. at 3–4. She had full bilateral upper and lower extremity strength against resistance in all flexors and extensors, but decreased sensation in her left upper and lower extremities and left face. *Id*. at 5.

Because Petitioner had transitioned to adult care, she was transferred to Houston Methodist Hospital, where she was admitted on September 1, 2015, for complaints of weakness and numbness in her legs for two days after receiving a Tdap vaccination. Ex. 7 at 136–37, Ex. 8 at 6. Neurologist Robert Smith, M.D., evaluated Petitioner following her admission for possible GBS. *Id.* at 140. Upon examination, Petitioner had mild right facial weakness. *Id.* at 141. Her motor exam showed full strength in the right upper and lower extremities, but reduced strength in the left upper and lower extremities. *Id*. The differential diagnosis included acute disseminated encephalomyelitis and GBS, along with "possible nonorganic cause of weakness." *Id*.

A lumbar puncture done on September 2, 2015, revealed normal protein and glucose and no oligoclonal bands. Ex. 7 at 302–03, 309. The brain MRI done that same day was also unremarkable. *Id*. at 185. However, EMG/NCS testing yielded abnormal results, showing decreased F-waves. Ex. 9 at 48–49. Dr. Smith initiated treatment with IVIG based on these results and evidence of decreased reflexes. Ex. 7 at 146.

On September 4, 2015, a note in Petitioner's neurology evaluation states that Ms. Dennington had 4+/5 strength in the left upper and lower extremities with normal strength on the right and a decreased 1+/4 reflex at the left knee, a normal 2+/4 reflex at the right knee, and absent reflexes at the ankles bilaterally. Ex. 7 at 150. The note also indicated that Petitioner had mild objective weakness and subjective numbness on the left side and because of her history of a previous episode of the Miller-Fisher variant of GBS, there was concern about a recurrence and she was to receive five doses of IVIG. *Id.*

Evolution of Treatment

Over the course of her treatment with IVIG, Petitioner reported that her symptoms were improving. Ex. 7 at 151–52, 154. Petitioner was discharged home on September 6, 2015, after completing five IVIG doses. *Id*. at 171, 369–70. Her discharge note included a "concern [] for a possible recurrence of GBS." *Id.* at 369–70.

Petitioner followed up with Dr. Smith on October 13, 2015, to evaluate her for chronic inflammatory demyelinating polyradiculoneuropathy ("CIDP"). Ex. 9 at 39. Dr. Smith noted that Petitioner was being seen for evaluation of "recurrent GBS vs CIDP, relapsing type after hospitalization." *Id*. He noted that Petitioner's first episode of weakness occurred ten years prior following a Tdap vaccination and "presumed viral infection with diarrhea/flulike [sic] [symptoms]." *Id*. "Following repeat [Tdap in 2015] . . . [Petitioner] developed identical prodrome of flu-like symptoms and diarrhea for several days followed by weakness." *Id.* Dr. Smith also noted that Petitioner had recovered from her earlier episode of GBS, "only for recurrent episode with similar activating stimulus." *Id*. He further noted the possibility of a diagnosis of CIDP, with onset in 2015 with "exacerbation following similar activator." *Id*.

Upon examination, Ms. Dennington displayed fatiguing nystagmus, abnormal facial expression and weakness, decreased hearing to finger rub, decreased reflexes, and decreased sensation to light touch in all extremities. Ex. 9 at 41. Dr. Smith assessed Petitioner with worsening CIDP, noting that while Petitioner and her mother do not feel that she has worsened, she had continued deficits and "slightly worsened proximal weakness" upon examination. *Id*. at 42. Her reflexes had returned in the lower extremities, but remained suppressed in the upper extremities. *Id.* Dr. Smith prescribed IVIG two days per month and referred Petitioner to physical therapy. *Id*.

Petitioner underwent a physical therapy evaluation at Kindred Rehabilitation Hospital on October 29, 2015. Ex. 2 at 4. She had nerve tingling in her face and muscle weakness. She wanted to improve her balance and increase her endurance. *Id.* Petitioner participated in three additional therapy sessions between November 5 and 12, 2015, and then "discharged herself due to the long drive to therapy" on November 17, 2015. *Id*. at 9.

Petitioner followed up with Dr. Smith on December 10, 2015, for bilateral hearing loss, CIDP, and mild memory loss. Ex. 9 at 35. She had begun IVIG treatment again, and noted that her previous facial sensory dysesthesias had resolved, with improved limb endurance as well. *Id*. However, she continued to have problems maintaining her posture and had problems with balance. *Id.* Dr. Smith discussed a neuropsychology referral as Petitioner had "baseline deficits from previous postvaccination event; though is fully functional." *Id*. at 37. Dr. Smith also noted "Description of Topics Counseled: Vestibular rehabilitation. When is GBS actually CIDP, and when can therapy for chronic problem help repair in recurrent but inactive process. [Central nervous system] involvement in post-vaccination [central and peripheral nervous system] injury." *Id.* at 37–38. Dr. Smith gave Petitioner a referral for physical and occupational therapy and ordered an EMG/NCS. *Id*.

Petitioner saw Dr. Smith in a follow-up for recurrent GBS on March 16, 2016. Ex. 9 at 31. Due to insurance reasons, Petitioner was not getting IVIG. *Id*. She was clinically stable but had evidence of incomplete resolution of problems with limb posture and endurance. *Id*. Dr. Smith noted that Ms. Dennington had a "mildly depressed affect" and on neurologic examination found ongoing weakness in multiple muscles and muscle groups in the upper and lower extremities. *Id.* at 33–34. His assessment was GBS, bilateral hearing loss (due to initial episode of GBS), and mild memory disturbance from "post episode of post-vaccination GBS+ . . . with balance and memory changes similar to those from previous episode 10 years earlier." *Id.* at 34.

A repeat EMG/NCS on April 6, 2016, showed evidence of a "diffuse polyradiculopathy with previous denervation and incomplete reinnervation." Ex. 35 at 7–9. On May 25, 2016, Dr. Smith noted that "for a variety of reasons" after November, Petitioner was no longer receiving IVIG. Ex. 9 at 27. However, she had remained stable with slow improvement in strength and endurance. *Id.*

In December 2016, Dr. Smith noted that Petitioner's most recent EMG "documented no new active lesions (not ongoing CIDP), but still showed evidence of distal demyelination - residual yet to recover from her most recent episode of weakness." Ex. 9 at 3. Dr. Smith noted persistent deficits in fatigue, endurance, and focus, with milder deficits in weakness and sensory function. *Id*. at 12. Dr. Smith indicated that he had written a letter documenting Petitioner's deficits to be used in her appeal to "government agencies involved in her oversight." *Id*. Petitioner's condition and assessment at her May 2017 visit with Dr. Smith was essentially unchanged. *Id*. at 16–25.

On May 25, 2018, Petitioner had a follow-up visit with Dr. Smith for evaluation of recurrent GBS. Ex. 9 at 27–30. It noted that she was stable and slowly improving in strength and duration over the past five months. *Id.* Physical examination showed weakness of the facial muscles that was more pronounced on the right resulting in some asymmetry, ongoing weakness of the extremities, and decreased to absent reflexes except at the knees. *Id.* Dr. Smith's assessment was GBS, though Petitioner "[i]nitially [had] some features suggestive of CIDP. . ." with lower facial weakness due to recurrent GBS, and bilateral hearing loss after her initial episode of GBS. *Id.* at 30.

The most recent visit with Dr. Smith in the records provided was on March 13, 2019. Ex. 20 at 18. Petitioner was no longer working (which had helped to reduce her anxiety level) and was receiving Social Security disability compensation. *Id.* at 18–19.

II. Expert Reports

A. *Petitioner's Expert – Carlo Tornatore, M.D.*

Dr. Tornatore, a board-certified neurologist, prepared two written reports for Petitioner in support of the contention that the Tdap vaccine can cause GBS, and that it did so in this case. Report, dated April 5, 2021, filed as Ex. 36 (ECF No. 38-1) ("Tornatore First Rep."); Report, dated January 10, 2022, filed as Ex. 38 (ECF No. 43-1) ("Tornatore Second Rep.").

Dr. Tornatore graduated from Cornell University with a Bachelor of Arts in Neurobiology, and attended Georgetown University Medical Center, where he received a Master of Science in Physiology. *Curriculum Vitae,* filed as Ex. B on April 5, 2021 (ECF No. 42-21) ("Tornatore CV") at 2. He subsequently graduated from medical school at Georgetown University School of Medicine, completing a residency in the Department of Neurology at Georgetown University Hospital. *Id*. He also completed a fellowship in molecular virology at the National Institute of Health in Bethesda, Maryland. *Id.* Dr. Tornatore has published multiple articles addressing cell biology and pathology of demyelinating disorders. *Id.* at 8–16. Currently, he serves as Professor and Chairman of the Department of Neurology at Georgetown University Medical Center, Chairman and Neurologist-in-Chief of the Department of Neurology at Medstar Georgetown University Hospital in Washington, D.C., and Executive Director of the Multiple Sclerosis Patient Centered Specialty Home. Tornatore First Rep. at 1.

First Report

Dr. Tornatore opined that Petitioner has GBS, which he defined as an autoimmune demyelinating neuropathy of the peripheral nervous system. Tornatore First Rep. at 21–22. It is believed that foreign antigens (e.g., viral or bacterial infection or vaccination) result in activation

of the immune system—a normal mechanism to clear the offending antigen. *Id.* However, in rare cases, the activation is misdirected, and both the humoral and cellular arms of the immune system (the innate and adaptive responses, respectively) attack components of its own nervous system. *Id.* In the case of GBS, the target of the immune response is the myelin (and in some cases the axons) of the peripheral nervous system. *Id.* The resulting injury is manifested clinically by numbness and weakness of the extremities, truncal muscles and muscles of the face and neck. *Id.* Unilateral or bilateral facial weakness, as in Ms. Dennington's situation, is very typical of GBS. *Id.*

Dr. Tornatore went into great detail discussing Ms. Dennington's medical records in the context of a GBS diagnosis (with this summation consisting of the majority of his first report). Tornatore First Rep. at 2–20. He emphasized the fact that Petitioner had experienced two episodes of GBS—thus, he deemed the best characterization of her diagnosis to be "recurrent GBS." *Id.* at 21. Petitioner's first episode began on August 21, 2005, with characteristics of facial diplegia and motor weakness, and the second episode was on September 1, 2015, which occurred shortly after receiving the Tdap vaccine (on August 30, 2015), and was marked with "nearly identical" symptoms to the first episode. *Id.*; Ex. 6 at 11–15; Ex. 16 at 20. Petitioner's EMG results from September 2, 2015, indicated early acute proximal demyelination and normal cerebrospinal fluid ("CSF") protein levels, which was consistent with early GBS, according to Dr. Tornatore. Tornatore First Rep. at 13–14, 21; Ex. 9 at 48–49; C. Fokke et al., *Diagnosis of Guillain-Barré Syndrome and Validation of Brighton Criteria*, Brain 33, 41 (2014), filed as Ex. 50 (ECF No. 57-1) ("Fokke"). And although one of Petitioner's treaters (Dr. Smith) felt the 2015 GBS occurrence had some characteristics of CIDP, Petitioner reached nadir within four weeks of onset—a defining feature of GBS. Tornatore First Rep. at 21; Ex. 9 at 30, 39, 41.

Next, Dr. Tornatore explained how the Tdap vaccine could theoretically cause GBS. Tornatore First Rep. at 22–24. The pathogenesis of GBS, Dr. Tornatore contended, is affected by molecular mimicry post-exposure to viral or bacterial antigens (which in turn resemble or mimic, host structures—meaning antibodies to the foreign antigens mistakenly attack the self). *Id.* at 22; R. Hughes & D. Cornblath, *Guillain-Barré Syndrome*, 366 Lancet 1653, 1658 (2005), filed as Ex. 39 (ECF No. 47-1). The concept of molecular mimicry is well-established in immunology. Tornatore First Rep. at 23; M. B. A. Oldstone, *Molecular Mimicry, Microbial Infection, and Autoimmune Disease: Evolution of the Concept*, 296 Current Topics Microbiology & Immunology 1, 3, 13 (2005), filed as Ex. 40 (ECF No. 47-2); T. Komagamine & N. Yuki, *Ganglioside Mimicry as a Cause of Guillain-Barré Syndrome*, 5 CNS & Neurological Disorders - Drug Targets 391, 395–96 (2006), filed as Ex. 52 (ECF No. 57-3) (discussing molecular mimicry in the context of autoimmune neuropathies and *Campylobacter jejuni*).

Of relevance to the discussion of vaccinations, Dr. Tornatore noted that GBS has been discussed in association with swine flu and tetanus vaccines. L. Schonberger et al., *Guillain-Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States,*

1976–1977, 110 Am. J. Epidemiology 105, 120–22 (1979), filed as Ex. 42 (ECF No. 47-4) ("Schonberger"). Additionally, other studies suggest that vaccines other than the flu vaccine can be associated with GBS. N. Souayah et al., *Guillain-Barre Syndrome After Vaccination in United States: A Report from the CDC/FDA Vaccine Adverse Event Reporting System (1990–2005)*, 11 Neuromuscular Disease 1, 5 (2009), filed as Ex. 45 (ECF No. 47-7) ("[o]ur results suggest that vaccines other than influenza vaccine can be associated with GBS."). He also cites case reports of autoimmune peripheral neuropathies following other vaccines. F. E. Shaw et al., *Postmarketing Surveillance for Neurologic Adverse Events Reported After Hepatitis B Vaccination,* 127 Am. J. Epidemiology 337, 344–50 (1988), filed as Ex. 44 (ECF No. 47-6) ("Shaw"); M. Khamaisi et al., *Guillain-Barré Syndrome Following Hepatitis B Vaccination*, 22 Clinical & Experimental Rheumatology 767, 768–69 (2004), filed as Ex. 51 (ECF No. 57-2) ("Khamaisi"). Overall, due to the recognized biological mechanisms discussed, Dr. Tornatore opined that the Tdap vaccine more likely than not could result in autoimmune peripheral nerve demyelination clinically presenting as GBS. Tornatore First Rep. at 24.

Dr. Tornatore maintained that Petitioner's medical history was consistent with his causation theory. Tornatore First Rep. at 21. Petitioner had no antecedent events to her second episode of GBS other than the Tdap vaccination. *Id.* Additionally, one of Petitioner's treaters, Dr. Smith, seemed in records to allude to the possibility of vaccine-induced GBS (despite some contentions that Ms. Dennington had characteristics of CIDP). *Id.*; Ex. 9 at 34, 39.

Finally, Dr. Tornatore deemed the timeframe for Petitioner's symptoms onset—within 48 hours of vaccination—to be medically acceptable. Tornatore First Rep. at 24–25; Ex. 6 at 11–15; Ex. 7 at 136–37. He opined that since her immune system was previously primed by earlier exposure to the Tdap vaccine, a quick response to a second antigenic challenge could be anticipated within 24 hours, so the rapidity with which Ms. Dennington's symptoms was consistent with that timeframe. Tornatore First Rep. at 24. To support this assertion, he relied on literature discussing the acceleration of the immune response after previous exposure, and most notably a piece of literature cited widely in the Program that is over forty years old, and which I have previously discussed relies on a flu vaccine that has not generally been administered since the 1970s. Schonberger at 105 (reviewing the onset of inflammatory demyelinating polyneuropathies following swine flu vaccination).[9]

[9] Dr. Tornatore also referenced two other items of literature, although one was not filed and the other did not reference the assertions he claimed (by my estimation, and due to the misfiling of specific pages). Tornatore First Rep. at 25; *See generally* Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality* 39, 39–54 (Kathleen R. Stratton et al., eds., 2011), filed as Ex. 47 (ECF No. 47-9) ("IOM Report") (discussing the assessment of epidemiologic, clinical, and biological evidence in regard to determining a causal relationship between vaccination and injury, but *not* the assertions Dr. Tornatore stated regarding timeframe).

Second Report

Dr. Tornatore's Second Report endeavored specifically to defend GBS as the proper diagnosis. Tornatore Second Rep. at 1–3. He noted that Petitioner's September 2, 2015 EMG results evidenced the presence of an acute inflammatory process of the proximal nerve roots. Ex. 9 at 48–49. Petitioner was also treated with five doses of IVIG immediately following her EMG report—the standard of care for GBS. Ex. 7 at 171, 396–70. A follow-up EMG on April 6, 2016, showed evidence of improvement, which was another indicator to Dr. Tornatore that Petitioner had GBS (since it bulwarked both the effectiveness of the immunotherapy treatment plus the monophasic course of her illness). Ex. 9 at 27.

Respondent's expert, Dr. Timothy Vartanian, had disagreed with Dr. Tornatore's assessment that Petitioner had a recurrent autoimmune neuropathy, but Dr. Tornatore's opinion remained unchanged. Tornatore Second Rep. at 2–3. Dr. Tornatore noted, for example, her discharge status on September 6, 2015, which expressed a "concern for a possible recurrence of GBS," and a note from Dr. Smith that when Petitioner was hospitalized the differential indicated "recurrent GBS vs. CIDP." Ex. 7 at 370; Ex. 9 at 39.

In regard to his medical theory, Dr. Tornatore pointed out that Dr. Vartanian did not dispute the scientific mechanisms of molecular mimicry as a scientific principle, suggesting he concurred that it was reputable. Dr. Tornatore Second Rep. at 4; Vartanian Rep. at 14. And although Dr. Vartanian asserted there was a lack of epidemiologic data to support an association between GBS and Tdap, Dr. Tornatore argued that epidemiology cannot rule out rare events such as vaccine injuries. Tornatore Second Rep. at 4.

Finally, with regard to onset, Dr. Tornatore disagreed with Dr. Vartanian's assessment that the immune response could not result in a neurologic injury within 48 hours of vaccination. Tornatore Second Rep. at 4. Rather, immediately after re-exposure to a foreign antigen, there is a measurable increase in the immune response, thus making Petitioner's onset of symptoms medically acceptable. *Id.*

B. *Respondent's Expert – Timothy Vartanian, M.D., Ph.D.*

Dr. Vartanian, a board-certified neurologist with subspecialties in caring for patients with inflammatory demyelinating diseases, prepared one written report for Respondent in support of the contention that there is not a casual association between the Tdap vaccine and GBS. Report, dated September 30, 2021, filed as Ex. A (ECF No. 41-1) ("Vartanian Rep.").

Dr. Vartanian received his bachelor's degree from Oakland University, along with his medical and doctorate degree from the University of Chicago. *Curriculum Vitae,* filed as Ex. B on

November 8, 2021 (ECF No. 42-21) ("Vartanian CV") at 1; Vartanian Rep. at 1. He completed a residency at Massachusetts General Hospital in Neurology. Vartanian CV at 2; Vartanian Rep. at 1. He then completed two fellowships, the first at Beth Israel Hospital and the second at Harvard Medical School. Vartanian CV at 2. Since 2009, Dr. Vartanian holds positions as a Professor at Weill Cornell Medicine. and an attending neurologist at New York Presbyterian Hospital. Vartanian CV at 2; Vartanian Rep. at 1. He has published a substantial number of peer-reviewed articles. Vartanian CV at 11–23.

Like Dr. Tornatore, Dr. Vartanian engaged in a thorough review of Petitioner's medical history. Vartanian Rep. at 2–10. He noted that GBS is an acute inflammatory demyelinating polyneuropathy typically triggered by an antecedent infection. *Id.* at 12. A classic clinical history is that of an individual who suffers a common infection and then two weeks later begins to note weakness in their distal lower limbs. *Id.*; P. van Doorn, *Diagnosis, Treatment and Prognosis of Guillain-Barré Syndrome (GBS)*, La Presse Médicale e193, e194 (2013), filed as Ex. A, Tab 17 (ECF No. 42-17) ("van Doorn").

Dr. Vartanian agreed that Petitioner's clinical presentation in 2005 was consistent with GBS. Vartanian Rep. at 11. Testing of Petitioner's CSF at that time showed acellularity and elevated protein levels—hallmarks of GBS. *Id.*; Ex. 16 at 20. Her presentation was asymmetric, and included an unusual finding with enhancement of the seventh and eighth nerve complex, resulting in uncommon facial symptoms, but case report evidence showed this was possible. Ex. 9 at 27; T. Takazawa et al., *Sudden Deafness and Facial Diplegia in Guillain-Barré Syndrome: Radiological Depiction of Facial and Acoustic Nerve Lesions*, 51 Internal Med. 2433, 2437 (2012), filed as Ex. A, Tab 16 (ECF No. 42-16).

In 2015, Petitioner's EMG/NCS also revealed characteristic findings associated with GBS. Vartanian Rep. at 11; Ex. 9 at 48–49. Dr. Vartanian maintained, however, that subsequent testing and the medical record did not establish evolution of her symptoms suggestive of new autoimmune or inflammatory demyelination. Vartanian Rep. at 11; Ex. 9 at 48–49. Petitioner's clinical course, coupled with results of repeat EMGs, did not support the conclusion that Petitioner experienced a recurrent autoimmune neuropathy characterized as GBS, although Dr. Vartanian did not elaborate on what a correct diagnosis for her symptoms at this time might be. Vartanian Rep. at 11.

In addition, Dr. Vartanian maintained that there was an absence of a causal relationship between the Tdap vaccine and GBS (independent of his questions about the proper diagnosis). Vartanian Rep. at 14. He began with a discussion of molecular mimicry, which he allowed applies to many examples of autoimmunity triggered by infection. *Id.* at 12–13. In essence (and specific to demyelinating autoimmune illnesses like GBS), molecular mimicry occurs when a molecular

motif found in an infectious or foreign agent[10] resembles a similar motif present in the peripheral nervous system myelin, raising the potential that antibodies generated against the foreign antigen will mistakenly attack the peripheral myelin. *Id.* at 13.

However, Dr. Vartanian maintained, reliable literature[11] did not support the contention that the Tdap vaccine could instigate an autoimmune process mediated by molecular mimicry and lead to GBS. *See, e.g.*, Vartanian Rep. at 14–16; W. Yih et al., *An Assessment of the Safety of Adolescent and Adult Tetanus–Diphtheria–Acellular Pertussis (Tdap) Vaccine, Using Active Surveillance for Adverse Events in the Vaccine Safety Datalink*, 27 Vaccine 4257, 4261 (2009), filed as Ex. A, Tab 18 (ECF No. 42-8) ("Yih") ("[w]e found no evidence of an association between Tdap and any of the five predefined adverse events [including GBS] in a surveillance period that included 660,245 doses of Tdap over the course of 145 weeks"); J. Nelson et al., *Adapting Group Sequential Methods to Observational Postlicensure Vaccine Safety Surveillance: Results of a Pentavalent Combination Dtap-IPV-Hib Vaccine Safety Study*, 177 Am. J. Epidemiology 131, 131 (2013), filed as Ex. A, Tab 13 (ECF No. 42-13) ("Nelson") ("[n]o increased risk was detected among 149,337 DTaP-IPV-Hib vaccinees versus historical comparators for any outcome, including . . . Guillain-Barré syndrome . . . ."); J. Tuttle et al., *The Risk of Guillain-Barre Syndrome After Tetanus-Toxoid-Containing Vaccines in Adults And Children in The United States*, 87 Am. J. Public Health 2045, 2045–47 (1997), filed as Ex. D (ECF No. 58-1) (concluding that if an association exists, it must be extremely rare and not of public health significance); M. Daley et al., *Safety of Diphtheria, Tetanus, Acellular Pertussis and Inactivated Poliovirus (Dtap–IPV) Vaccine*, 32 Vaccine 3019, 3019 (2014), filed as Ex. A, Tab 6 (ECF No. 42-6) ("Daley") (". . . there was no evidence of increased risk for any of the pre-specified adverse events monitored."); R. Baxter et al., *Lack of Association of Guillain-Barre Syndrome with Vaccinations*, 57 Clinical Infection Diseases 197, 197 (2013), filed as Ex. A, Tab 1 (ECF No. 42-1) ("Baxter") (finding no evidence of an increased risk of GBS following vaccinations of any kind).

In addition, Dr. Vartanian maintained that Petitioner's medical history was unsupportive of the conclusion that the Tdap vaccine had caused her injury. Vartanian Rep at 11. He noted that the etiology of Petitioner's earlier GBS case in 2005 was mistakenly attributed to a vaccination that the record did not corroborate as having occurred, while the notes contemporaneous with that

[10] Most commonly in GBS, the infectious agent is bacterial, viral, or fungal. Vartanian Rep. at 14. Half the time an antecedent infection is not reported nor is there recent vaccination, and in these cases, it is thought that subclinical infection is driving autoimmunity. *Id.*

[11] One piece of literature Dr. Vartanian referenced was an IOM Report, but it was not filed by Respondent (and as noted earlier Petitioner did not cite to the accurate page numbers to support this assertion). However, some of Respondent's literature cites to IOM Reports, which (according to those authors) found the evidence inadequate to accept or reject a causal relationship. S. Chang et al., *U.S. Postlicensure Safety Surveillance for Adolescent and Adult Tetanus, Diphtheria and Acellular Pertussis Vaccines: 2005–2007*, 31 Vaccine 1447, 1450 (2013), filed as Ex. A, Tab 3 (ECF No. 42-3). Ultimately, the fact that the IOM report *itself* was not filed means I cannot give such contentions much weight in my overall analysis.

presentation acknowledged the possibility of multiple antecedent infections. *Id.*; Ex. 16 at 20. Similar evidence of an antecedent infection was present in the record from her 2015 GBS incident. Vartanian Rep. at 10 (citing a wound on her foot from a nail and reporting a subjective fever and nausea). Dr. Vartanian also noted that antecedent gastrointestinal or respiratory infections are widely understood by medical science to be closely associated with GBS, whereas the Tdap vaccine has only anecdotal associations. Vartanian Rep. at 11; Baxter at 197. Thus, a prior infection was the most likely explanation for *both* instances of Petitioner's GBS. *Id.*

Dr. Vartanian's opinion also included consideration of Petitioner's onset and its relationship to causation. Although the adaptive immune system can provide a quick response in the event the body has previously encountered the same pathogen (or vaccine) previously, there is still a limit to how quickly a memory response will result in an effective immune reaction. Vartanian Rep. at 16–17. Here, the record established that Petitioner's onset began one and a half days after her vaccination, which Dr. Vartanian deemed too little time for humoral or cellular immunity to cause an injury to the nervous system. *Id.*[12]

III. Procedural History

After the case's initiation in August 2018, Petitioner filed medical records supporting the claim, and then Respondent's Rule 4(c) Report was filed on November 21, 2019 (ECF No. 22). The case was assigned to me in January 2021. Expert reports were filed through January 2022. Thereafter I set a schedule for a ruling on the record, and the parties acceded to this method of resolution. The parties had fully briefed the matter by August 2022, and it is now ripe for resolution.

IV. Parties' Arguments

Petitioner argues that she was correctly diagnosed with a recurrent autoimmune neuropathy (GBS) based on treater encounters. Mot. at 18–22; Reply at 2–3. Petitioner also maintains that she has met the causation-in-fact burden based on the factors established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274 (Fed. Cir. 2005); Mot. at 22–33; Reply at 3–9. Statements from Petitioner's expert, she purports, support the contention that the Tdap vaccine can cause GBS via molecular mimicry. Mot. at 25–26; Reply at 3–7. This determination is also supported by prior Program decisions. *See Mohamad v. Sec'y of Health & Hum. Servs.*, No. 16-1075V, 2022 WL 711604, *17–18 (Fed. Cl. Spec. Mstr. Jan. 27, 2022).

Ms. Dennington next claims that she has demonstrated a logical sequence of cause and effect that the Tdap vaccine "did cause" her injury. Mot. at 27–31; Reply at 7–8. In support, she notes that treating physicians allowed for the possibility that the vaccine was related to her injuries.

[12] Dr. Vartanian also cited to a "Abolhassani 2020" article in support of this contention, but it was not filed.

Mot. at 31. Petitioner and her mother also report that shortly before the onset of GBS symptoms in 2005, Petitioner had received a tetanus vaccine and had a flu-like illness—not coincidental, in Petitioner's view, and demonstrated evidence of a rechallenge.[13] Mot. at 27–29; Reply at 7. This makes it likely that Petitioner experienced a quick onset of symptoms after her second vaccine exposure because her immune system was previously primed with the tetanus toxoid antigen. Mot. at 29–30; Reply at 8. Additionally, Petitioner observes that she presented with similar symptoms in 2015 as she did in 2005. Mot. at 30–31. Finally, the timing of her onset—approximately 48 hours after receiving her Tdap vaccine—is medically-acceptable. Mot. 31–33; Reply at 8–9.

In opposing entitlement, Respondent questions the factual basis for the alleged injury, maintaining that Ms. Dennington's test results and medical records are not consistent with recurrent GBS (or GBS generally for that matter). Opp. at 16–17. Additionally, Petitioner has not preponderantly established a reliable medical theory causally connecting her vaccination to GBS. *Id.* at 18. Petitioner relies on the theory of molecular mimicry too generally and does not support such assertions with reliable literature specific to the Tdap vaccine. *Id.* at 18–19. Respondent also cites to previous cases involving the Tdap vaccine and GBS, in which petitioners failed to produce reliable scientific evidence to establish causation. *See, e.g.*, *Tompkins v. Sec'y of Health & Hum. Servs.,* No. 10-261V, 2013 WL 3498652 (Fed. Cl. Spec. Mstr. June 21, 2013), *mot. for review den'd,* 117 Fed. Cl. 713 (2014); *Isaac v. Sec'y of Health & Hum. Servs*., No. 08-601V, 2012 WL 3609993 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x 999 (Fed. Cir. 2013). Respondent distinguishes these cases from *Mohamad,* where Respondent effectively conceded *Althen* prong one (despite the special master not finding the theory persuasive), and where the matter turned on literature not offered in this case. Opp. at 20; *Mohamad*, 2022 WL 711604, *17–18.

Under *Althen* prong two, Respondent argues, Petitioner's reported onset occurred in the context of an upper respiratory infection (along with other symptoms), which is more likely the cause of her injury. Opp. at 21–22. Petitioner's rechallenge argument is not supported by the medical records as there was no indication of *any* vaccine received by Petitioner prior to the onset of Petitioner's symptoms in 2005. *Id.* at 21. And Petitioner's showing under *Althen* prong three also fails because it relies on evidence linking GBS and the 1976 H1N1 *flu* vaccine—a completely different vaccine that does not contain any aluminum adjuvant. *Id.* at 24. Otherwise, onset would be expected to occur within four days[14] at the soonest, but Petitioner's reported symptoms occurred

[13] *See generally Nussman v. Sec'y of Health & Hum. Servs.*, No. 99-500V, 2008 WL 449656, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 2008), *aff'd,* 83 Fed. Cl. 111 (2008) (defining challenge-rechallenge as "when a person (1) is exposed to one antigen, (2) reacts to that antigen in a particular way, (3) is given the same antigen again, and (4) reacts to that antigen similarly").

[14] As noted earlier, Dr. Vartanian's citation to "Abolhassani 2020" was referenced to support this timeframe, but this literature was never filed.

two days after vaccination, which does not fit with the current understanding of immunology and neurology. *Id.*

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[15] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

[15] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)); *Howard v. Sec'y of Health & Hum. Servs.*, No. 16-1592V, slip op. (Fed. Cl. Feb. 27, 2023) (affirming dismissal of a Tdap-CIDP case, and confirming that "[t]he standard has been preponderance for nearly four decades"). Otherwise, petitioners *always* have the ultimate burden of establishing their Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a

'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained

in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be

more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed

every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, and the parties have not challenged my determination to do so. Mot. at 1; Opp. at 1. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. An Overview of Relevant Medical Terms and Applicable Prior Decisions

GBS has been defined as an acute, monophasic peripheral neuropathy involving rapidly progressive and ascending motor neuron paralysis, which is thought to have an autoimmune mechanism. Fokke at 34. Increased protein levels in the cerebral spinal fluid without a corresponding increase in cells is often featured in GBS. *Id*. Its characteristics typically include generalized muscle weakness combined with sensory symptoms. van Doorn at e195. GBS has an acute onset, is monophasic, and is not steroid-responsive. *Id.* at e198.

There is a large body of reasoned decisions[16] affirming the existence of an association between the flu vaccine and peripheral neuropathies—most often GBS. Indeed, GBS occurring after receipt of a flu vaccine is the basis for a Table claim. 42 C.F.R. § 100.3.14. This means the Government has agreed that sufficiently-probative and reliable science on the topic existed to

[16] Although prior decisions from different cases do not control the outcome herein, special masters may reasonably take into account, for guidance, the logic of reasoned entitlement determinations. In fact, it is wise to do so, given how often similar causation theories or fact patterns arise in Vaccine Program cases.

justify conceding causation, at least for Program purposes. *Haskins v. Secretary of Health & Hum. Servs.*, No. 18-1776, 2020 WL 1870279 (Fed. Cl. Spec. Mstr. Mar. 13, 2019). Indeed, even in cases where a Table element for a flu vaccine-GBS claim cannot be met (for example, when onset is too short or long to fit within the timeframe of 3-42 days set for the claim), any subsequent causation-in-fact analysis does not usually turn on the "can cause" first *Althen* prong. *See Welch v. Sec'y of Health & Hum. Servs.*, No. 18-494V, 2019 WL 349360 (Fed. Cl. Spec. Mstr. July 2, 2019).

Other vaccines have also been found causal of GBS, although there is disagreement among the special masters as to the preponderant strength of these associations. *See, e.g.*, *Gross v. Sec'y of Health & Hum. Servs.*, No. 17-1075V, 2022 WL 9669651, at *36–37 (Fed. Cl. Spec. Mstr. Sept. 22, 2022) (showing the pneumococcal vaccine caused GBS); *but see Trollinger v. Sec'y of Health & Hum. Servs.*, No. 16-473V, 2023 WL 2521912, at *30 (Fed. Cl. Spec. Mstr. Feb. 17, 2023), *appeal docketed*, No. 16-473V, (Fed. Cl. Mar. 17, 2023) (finding that the pneumococcal vaccine was not shown to cause GBS); *Bielak v. Sec'y of Health & Hum. Servs.*, No. 18-761V, 2022 WL 18058244, at *34 (Fed. Cl. Spec. Mstr. Dec. 9, 2022) (same). It thus cannot be said that the Program has developed a consistent view as to what the science preponderantly "says" about causation when the flu vaccine is not involved. Instead, it appears that the outcome in such cases is mostly a function of the evidence before the special master with no clear trend one way or the other.

This is definitely true in the context of claims that the Tdap vaccine can cause GBS. Several cases decided in the past ten years found *no causal association* between the two. *See, e.g.*, *Winkler v. Sec'y of Health & Hum. Servs*., No. 18-203V, 2021 WL 6276203 (Fed. Cl. Spec. Mstr. Dec. 10, 2021), *mot. for review den'd*, 2022 WL 1528779 (2022); *Montgomery v. Sec'y of Health & Hum. Servs.*, No. 15-1037V, 2019 WL 2511352 (Fed. Cl. Spec. Mstr. May 21, 2019); *Tompkins*, 2013 WL 3498652; *Isaac,* 2012 WL 3609993.[17]

In *Isaac*, for example, the petitioner offered molecular mimicry as her causal theory. *Isaac*, 2012 WL 3609993, at *6. But the special master determined that Dr. Tornatore (who also served as that petitioner's expert) had over-relied on a case report[18] and there was an absence of focus on molecular mimicry as a theory of vaccine injury—an allegation also made by Respondent in this case. *Id.* at *20–21. This determination was affirmed on appeal at the Court of Federal Claims and Federal Circuit. In *Tompkins*, the special master denied entitlement in a case alleging that a number

[17] I have also decided a few cases finding no causal association between the Tdap vaccine and CIDP—albeit a different injury from GBS. *See, e.g.*, *Howard v. Sec'y of Health & Hum. Servs.*, No. 16-1592V, 2022 WL 4869354 (Fed. Cl. Spec. Mstr. Aug. 31, 2022), *mot. for review den'd*, slip op. (Fed. Cl. Feb. 27, 2023); *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 18-1012V, 2022 WL 1013264, at *1 (Fed. Cl. Spec. Mstr. Mar. 11, 2022).

[18] The case report in *Isaac* was also briefly referred to in this case. *See* J.D. Pollard & G. Selby, *Relapsing Neuropathy Due to Tetanus Toxoid,* 37 J. Neurol. Sci. 113 (1978), filed as Ex. 43 (ECF No. 42-5).

of vaccines received at the same time, including the Tdap vaccine, caused a petitioner's GBS, but the causal theory put forward attempted to assert that the vaccines could also individually trigger the disease. *Tompkins*, 2013 WL 3498652, at *15. The petitioner's expert, however, relied heavily on VAERS passive surveillance data,[19] and otherwise invoked a number of theories (molecular mimicry, or endotoxin in tetanus-containing vaccines) that were only cursorily discussed. *Id.* at *19–23.

Several cases go the other way, as Petitioner notes. In *Mohamad*, a special master ruled in the petitioner's favor in a Tdap-GBS case, but almost wholly based on determination that the Government had conceded the first *Althen* prong, while also emphasizing evidence of *prior* post-vaccination demyelination, suggesting proof of "rechallenge." *See Mohamad v. Sec'y of Health & Hum. Servs.*, No. 16-1075V, 2022 WL 711604, at *18 n.17 (Fed. Cl. Spec. Mstr. Jan. 27, 2022); *see also Swaiss v. Sec'y of Health & Hum. Servs.*, No. 15-286V, 2019 WL 6520791, at *23-27 (Fed. Cl. Spec. Mstr. Nov. 4, 2019) (determining a small fiber neuropathy (characterized in Swaiss as "a variant" of GBS) could be caused by the Tdap vaccine via the mechanism of molecular mimicry, but acknowledging that the evidence offered to associate GBS and Tdap generally was somewhat lacking). Most recently, a special master granted entitlement, but heavily focused on a discussion of certain reports issued by the Institute of Medicine (some of which were not filed here), and only briefly analyzed petitioner's theory, which relied on theories other than molecular mimicry. *Harris v. Sec'y of Health & Hum. Servs.*, No. 18-944V, slip op. (Fed. Cl. Spec. Mstr. Feb. 21, 2023).

Thus, it certainly cannot be said that claims relying on the Tdap vaccine's association with GBS are categorically ruled out—even if it is also clear, at the threshold, that there is a meaningful decline in the amount of reliable scientific evidence associating that vaccine to this kind of nerve injury, when compared to what is known about GBS and the flu vaccine—and reason therefore to doubt that any putative association is well-founded.

II. Petitioner Has Preponderantly Established Her GBS Diagnosis

It is often appropriate for a special master to first determine which alleged injury is best supported by the evidence before applying the *Althen* test—particularly when the injury is

[19] The Vaccine Adverse Event Reporting System ("VAERS") is a national warning system designed to detect safety problems in U.S.-licensed vaccines. *See About VAERS*, VAERS, https://vaers hhs.gov/about html (last visited Mar. 23, 2023). It is managed by both the CDC and the FDA. VAERS monitors and analyzes reports of vaccine related injuries and side effects from both healthcare professionals and individuals. But it has been observed in the Program that VAERS data is not particularly probative of causation unless supplemented with other reliable evidence—since a VAERS report only establishes a temporal, post-vaccination occurrence, and thus shines no light on the possibility of causation itself. *See also Vig v. Sec'y of Health & Human Servs.*, No. 01–198V, 2013 WL 6596683, at *17 (Fed. Cl. Spec. Mstr. Nov. 14, 2013) ("VAERS is a stocked pond, containing only reports of adverse events after vaccinations but no data about the number of vaccines administered or the occurrence of the same adverse event in individuals who have not been vaccinated").

disputed—so that "the special master could subsequently determine causation relative to the injury." *Broekelschen*, 618 F.3d at 1346. In some cases, determining the injury obviates entirely the need for any *Althen* analysis, since the petitioner's claim, and causation theory, is dependent on a finding of a specific injury. *Id.*

In this case, the parties dispute the proper diagnosis. Opp. at 16–17. The record best supports Petitioner's contention, however. First, there is ample, trustworthy treater support for Petitioner's preferred diagnosis. Petitioner's treating neurologist, Dr. Smith, diagnosed Petitioner with GBS on numerous occasions. Ex. 7 at 136–37, 140–41, 150. Although Dr. Smith later included CIDP in his differential diagnosis in December 2015 (Ex. 9 at 37–39), he clarified a year later his view that Petitioner *did not* have "ongoing CIDP," since she had not displayed new active lesions, and was symptomatically stable (evidence of distal demyelination was residual in nature). Ex. 9 at 3, 30, 34. Although I am never bound to accept a treater's opinion, I may give weight to their views. *Snyder*, 88 Fed. Cl. at 746 n.67. Here, Petitioner consistently saw Dr. Smith, and he reached conclusions that seem reasonable based upon the records in which they are set forth.

Second, the medical records largely appear consistent with the conclusion that Petitioner was suffering from GBS. Petitioner underwent complete diagnostic workups, including labs, MRIs, a lumbar puncture, and EMG/NCS tests. This is the evidence upon which Dr. Smith relied. Dr. Tornatore also persuasively established that Petitioner presented with defining features of GBS—not CIDP. The latter diagnosis has ultimately limited support in the record, even if (due mostly to the recurrent aspect of Petitioner's GBS, especially since she experienced two separate instances of it over several years) CIDP was reasonably raised as a possibility.

Dr. Vartanian makes a number of points in opposition (citing to Petitioner's test results), but does not offer a more specific diagnostic view. He opined that results of Petitioner's EMG results showed evidence of her prior bout of GBS in 2005. However, Dr. Vartanian did not explain how such residual evidence would be revealed in Petitioner's test results ten years later. Dr. Vartanian otherwise did not fully substantiate his argument, and provided a lackluster explanation for why Petitioner did not have GBS despite her treaters and Dr. Tornatore, who more persuasively supported the diagnosis with record references. At bottom, the overall record preponderates in Petitioner's favor on diagnosis.

III. Petitioner Has not Carried Her Burden of Proof[20]

A. *Althen Prong One*

Petitioner has not established that the Tdap vaccine could cause GBS with sufficient reliable scientific or medical evidence. This does not mean that *some* of her causation contentions

[20] I address the three prongs in order of their importance to my decision.

lacked trustworthy or reliable support. The core concept of molecular mimicry is a reliable theory for how *some* autoimmune diseases occur, and it has in other contexts been persuasively connected to vaccination, which due to antigenic similarity between a vaccine component and self structure, could result in an autoimmune cross-attack.

However, I have now repeatedly observed in Program cases that more must be done to preponderantly establish causation than simply "raise the flag" of molecular mimicry as a generally-reliable concept. *See, e.g.*, *McKown v. Sec'y of Health & Hum. Servs.,* No. 15-1451V, 2019 WL 4072113, at *50 (Fed. Cl. Spec. Mstr. July 15, 2019) (citing *Devonshire v. Sec'y of Health & Hum. Servs.,* No. 99-031V, 2006 WL 2970418, at *15 (Fed. Cl. Spec. Mstr. Sept. 2006)) ("[b]ut merely chanting the magic words 'molecular mimicry' in a Vaccine Act case does not render a causation theory scientifically reliable, absent *additional evidence* specifically tying the mechanism to the injury and/or vaccine in question") (emphasis in original), *mot. for review den'd,* 76 Fed. Cl. 452 (2007)). Instead, claimants and their experts must provide sufficient connective evidence to allow a conclusion that it is "more likely than not" the specific vaccine in question that could cause the relevant injury.

Dr. Tornatore was well qualified to offer the opinion he did, but he did not attempt to establish the kind of homology between vaccine antigens and self structures in the nerves that is a common starting point for molecular mimicry when offered as a mechanistic explanation. He also pointed to no specific antibody created in response to the Tdap vaccine that might cross-react against nerve myelin in the manner GBS is believed to progress. Rather, he unpersuasively argued that because Dr. Vartanian did not dispute the scientific principles behind molecular mimicry, Respondent had effectively conceded the existence of a causal relationship between the Tdap vaccine and GBS. Tornatore Second Rep. at 14. But as noted above, molecular mimicry's reliability *per se* does not mean it explains how every covered vaccine could cause any autoimmune condition.

Dr. Tornatore also relied on case reports regarding peripheral neuropathies following *other* vaccinations to prove his theory. But it is well established that case report evidence is only weakly probative of causation. *See, e.g.*, *Pearson v. Sec'y of Health & Human Servs*., No. 17-489V, 2019 WL 1150044, at *11 (Fed. Cl. Spec. Mstr. Feb. 7, 2019) (concluding that case reports receive only limited evidentiary weight and cannot cure *Althen* prong one deficiencies); *Harris v. Sec'y of Health & Human Servs*., No. 10-322V, 2014 WL 3159377, at *18 (Fed. Cl. Spec. Mstr. June 10, 2014) ("case reports are generally not a valuable form of evidence"). And those Petitioner offered were not specific to the Tdap vaccine, further diminishing their evidentiary value. *See, e.g.*, Shaw at 344–50; Khamaisi at 768–79.

Dr. Vartanian, by contrast, offered a more persuasive argument on the causation side of the case than with respect to his diagnostic opinion. In particular, he referenced several pieces of

reliable literature which did not observe an association between the Tdap vaccine and injury. *See, e.g.*, Yih at 4261; Nelson at 131; Daley at 3019. While it is almost a bromide in Program cases that epidemiologic studies are never a *required* kind of proof that claimants must offer to meet their burden, they can be *considered* when they exist—and given weight if they are reliable and do not support causation, as here. *King v. Sec'y of Health & Hum. Servs.*, No. 03-584V, 2010 WL 892296, at *74 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) ("[c]onsistent with the teachings of *Daubert, Terran,* and *Grant,* special masters have routinely found that epidemiologic evidence, and/or other medical journal articles, while not *dispositive,* should be *considered* in evaluating scientific theories.").

This is not the first case in which a petitioner has unsuccessfully attempted to argue that the Tdap vaccine can cause GBS. While prior determinations do not determine the outcome, in the end I see no evidence offered herein more persuasive on this question than what I have previously considered. Even if it remains debatable whether this vaccine can have the same pathologic impact as evidence indicates the flu vaccine does, Petitioner's showing *in this case* is insufficient for me to find this *Althen* prong was satisfied.

B. *Althen Prong Three*

The experts agreed that Petitioner experienced onset occurring within 48 hours of vaccination, but disputed whether this timeframe was medically acceptable. Dr. Vartanian argued that the adaptive immune response cannot respond so quickly, whereas Dr. Tornatore found that an even more rapid response was acceptable (assuming that Petitioner had experienced rechallenge to the Tdap vaccine).

After review of the evidence, I deem Respondent's position more persuasive. An autoimmune cross-reaction with molecular mimicry as its mechanism would rely on an adaptive response (in which the immune system must first "see" the presenting antigen in the vaccine, then generate antibodies that can lead the attack on self nerve tissues)[21] that would not have run its course within two days such that symptoms of the demyelinating damage central to GBS would manifest. Such a short timeframe is simply too quick, as I have found in comparable cases. *See,* e.g., *Rowan v. Sec'y of Health & Hum. Servs.*, No. 17-760V, 2020 WL 2954954, at *17 (Fed. Cl. Spec. Mstr. Apr. 28, 2020) (36-hour onset for GBS after receipt of flu vaccine not medically acceptable).[22]

[21] I have previously described in detail how there is a "lag and log" phase in the adaptive immune response—"[l]ag begins the process and is the time during which the body encounters foreign antigens and through recognition of them initiates an adaptive process, while log is the phase when those antibodies are actually produced." *Rowan v. Sec'y of Health & Hum. Servs.*, No. 17-760V, 2020 WL 2954954, at *17 (Fed. Cl. Spec. Mstr. Apr. 28, 2020) (citing *Forrest v. Sec'y of Health & Human Servs.*, No. 14-1016V, 2019 WL 925495, at *6 (Fed. Cl. Spec. Mstr. Jan. 28, 2019)).

[22] I also note that the flu vaccine-GBS Table claim only concedes causation for GBS onsets occurring no sooner than *three* days post-vaccination. 42 C.F.R. § 100.3(a)(XIV)(D). Thus, even putting aside the *Althen* prong one deficiencies of this case, timing of Ms. Dennington's onset would remain problematic, as it was in cases like *Rowan.*

To evade this timeframe deficiency, Petitioner relied a bit on the concept of an immune memory response to the vaccine, based on the contention (uncorroborated by record proof) that Petitioner and/or her mother recalled her receiving a Tdap dose not long before her onset of 2005 GBS, thus establishing a "rechallenge" context (in which immune memory would result in a faster response). *See, e.g.*, Mot. at 27–29. But even if this vaccination event did occur, Dr. Vartanian persuasively established that a shorter response would still take *more* than two days to generate the relevant antibodies. In reaction, Dr. Tornatore attempted to substantiate his timing arguments by relying on Schonberger, an item of literature involving only to the flu vaccine, and one that is now more than 40 years old. Schonberger at 105. Nothing was offered by Petitioner on timing specific to the Tdap vaccine, and Petitioner's case reports discussing another vaccine's (Hep. B) GBS association in fact documented a *longer* onset timeframe than herein. *See, e.g.*, Shaw at 342 (documenting GBS cases occurring within seven weeks of the most proximate vaccine dose); Khamaisi at 767 (reporting that an individual developed GBS ten weeks after vaccination).

C. *Althen Prong Two*

There is treater support in Petitioner's medical records for a vaccine causal relationship, supportive of the "did cause" *Althen* prong. But I am not bound to accept a treater's opinion. *Snyder*, 88 Fed. Cl. at 746 n.67. Rather, I may weigh the basis for such a view, and need not take it at face value simply because it was rendered contemporaneously.

Here, it appears in several instances that treaters made this reference on the basis of representations by Petitioner or her mother that she had previously incurred post-vaccination GBS. *See* Ex. 8 at 3 ("per mom [patient] was seen at TCH in 2005 with same complaints"). But as even Petitioner admits, her 2005 records *do not establish* that she received the Tdap vaccine in 2005. Mot. at 28. Indeed, the records do not even document the "same" symptoms. In 2005, Petitioner reported that her symptoms began with a fever, headache, and neck pain before developing facial tingling and difficulty walking, whereas Petitioner's symptoms in 2015 began in the context of mild pain and chills due to a wound on her foot and a two-day history of a subjective fever and nausea, which later progressed to numbness and tingling in her lower extremities. Ex. 6 at 11, 29; Ex. 8 at 3; Ex. 16 at 2. I thus do not find that the relevant treater views of causality were *reasoned*, since they assumed a prior vaccine relationship when that underlying vaccination event cannot be substantiated.

Contentions about the "second" dose of Tdap vaccine constituting an immune rechallenge are also unavailing. Ex. 7 at 140, 154; Ex. 9 at 39. Dr. Tornatore's arguments about a shorter immune memory response (which in turn would allow for a shorter post-vaccination onset) relied on the accuracy of assertions that Petitioner received the vaccine in 2005, but the record does not

substantiate that allegation. And as noted above, I otherwise determine that *even* in the context of a rechallenge, onset would likely take more than two days.

Finally, I observe evidence in the record of a potential alternative explanation for her GBS that was not adequately explained by Petitioner.[23] It was noted that Petitioner's 2015 Tdap vaccination was due to a rash and abscess from an "old rusty pole," which could have caused an intercurrent infection. Ex. 6 at 29. Even Petitioner's own expert noted that foreign antigens like viral or bacterial infections can result in the activation of the immune system, and in rare cases cause the body to target its own nervous system. Tornatore First Rep. at 21–22. While I cannot conclude there *was* an alternative cause for her GBS, this evidence certainly undermines any contention that nothing else could explain it, especially since (as Dr. Vartanian maintained) evidence of antecedent infections causing GBS is much stronger than what links GBS to vaccines.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[24]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[23] Even though petitioners are never burdened with *disproving* an alternative cause in their primary case, they may not ignore alternative evidence undermining their *Althen* showing. *See Snyder v. Sec'y of Health & Hum. Servs.*, 553 F. App'x 994, 1000 (Fed. Cir. 2014) ("no evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute") (*quoting Stone v. Sec'y of Health & Hum. Servs*., 676 F.3d 1373, 1380 (Fed. Cir. 2012); *see also de Bazan*, 539 F.3d at 1353 ("[t]he government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief"). Thus, I consider this proof in weighing Petitioner's "did cause" success—although I do not give it substantial weight.

[24] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.